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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/760,476	01/21/2004	Steven Bernard	3659-79	9797
23117	7590	12/20/2005	EXAMINER	
NIXON & VANDERHYE, PC 901 NORTH GLEBE ROAD, 11TH FLOOR ARLINGTON, VA 22203			DEAK, LESLIE R	
			ART UNIT	PAPER NUMBER
			3761	
DATE MAILED: 12/20/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/760,476

Applicant(s)

BERNARD ET AL.

Examiner

Leslie R. Deak

Art Unit

3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

**DETAILED ACTION**

***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 2-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 2-9 recite the limitation "extracorporeal blood circuit as in claim 1" in line 1. There is insufficient antecedent basis for this limitation in the claim, since claim 1 refers only to an extracorporeal blood tube. For the purposes of examination, examiner has assumed that applicant is referring to the tube recited in claim 1.

***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-4 and 7-9 rejected under 35 U.S.C. 102(b) as being anticipated by US 3,882,862 to Berend.

Berend, in the specification and figures, discloses the apparatus as claimed by applicant. In particular, Berend discloses an arteriovenous shunt or tube for extracorporeal blood therapy. The shunt comprises a first and second Venturi tube 10,

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20, that narrows in diameter (see FIG 1). The tube comprises ends (generally 1<sup>st</sup> end at side 16, second end at side 12) that have a larger diameter than a center section (narrowed section generally at 10) with a tapered transition between the larger diameter and the smaller diameter. With regard to claim 4, Berend illustrates a shunt in FIG 1 sutured to a vein, wherein the tapered transition is less than 12 inches in length.

With regard to claims 7 and 8, Berend discloses that connectors 14a and 14b may be connected to a pump and dialyzer (see FIG 2, column 2, lines 55-67). In the illustration, tubular connector 14a has a larger diameter than tube 12, indicating that the tube connecting to the pump and dialyzer has a diameter greater than that of first and second end of venture tube 10.

With regard to claim 9, Berend discloses that the venture tube 10 may be molded to a piece of tubing 12 that terminates in a connector 14.

### ***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 5-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 3,882,862 to Berend.

Berend, in the specification and figures, discloses the apparatus substantially as claimed by applicant. In particular, Berend discloses an arteriovenous shunt for

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extracorporeal blood therapy. Berend fails to disclose the exact thickness or diameter of the tube. However, Berend discloses that the diameter of the tubes may be selected to match the diameters of the patient's artery and vein to provide undisturbed fluid flow. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to vary the inner and outer diameter of the tube (thus affecting the thickness of the tube) to achieve the values claimed by applicant, since not only may tube size be selected to match patient parameters, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. See MPEP 2144.05.

### ***Conclusion***

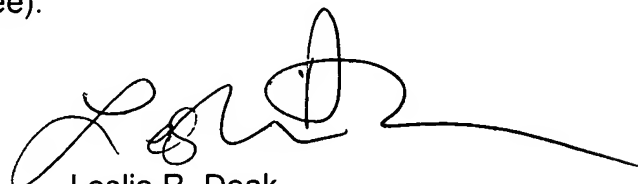
7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

- a. US 6,039,078 Tamari
  - i. Extracorporeal tube set with venture-shaped pressure control valve
- b. US 6,595,966 Davey
  - ii. Dialysis catheters that use diameter changes to control flow
- c. US 6,893,413 Martin
  - iii. Venturi-shaped stent combination

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 571-272-4943. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'Leslie R. Deak', with a long horizontal line extending to the right.

Leslie R. Deak  
Patent Examiner  
Art Unit 3761  
6 December 2005